

Petition.  
Docket number 2005A-0014/AP1  
Filed 8.12.2004 Advisory Opinion

1 AFJ

131.05  
date

Dennie L. Butler, Director (0175 S FEB-7 2005)  
Division of Dockets Management,  
Food and Drug Administration, Dept.  
of Health and Human Services, Rm 1061  
5630 Fishers Lane, Rockville, MD 20852

Draft - Referenced with Petition docket number 2005A-0014 / AP1  
Filed 8.12.2004 Advisory opinion.

All Draft documents submitted to the Division of docket management under (§10.65(h))

Draft Filed under Title 21 CFR 10.40 ch.1 4.1.04 Edition.

Section §10.40 Promulgation of regulations for the efficient enforcement of the law, specified in (§10.25) (§10.50) (§10.25(a)) (Administrative Procedure Act) (5 U.S.C. 551), (552) and (553) amended Mar 9, 2001 at 66 FR 12848.

Statement - Enforce draft because of this problem.

Experimental biomedical research performed on a incarcerated implant recipient with unfinished unauthorized device.

Sponsor and manufacturer didn't give implant recipient warning or caution statements and gave no device advice. The danger of implant.

I will Follow-up with court action.

The undersigned document is submitted under 10.65(h) for section 10.40 signed and submitted on Jan. 31, 2005 X Billy G. Pierson  
contact address,

Billy G. Pierson 90717

Enclosures \_\_\_\_\_  
F.D.A Jurisdiction  
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AP2

jurisdictionUnited States Courts of the Territories

{Title 5 United States Code - chapter 7 sec. 553  
 {Title 18 United States Code - chapter

CLASSIFICATION

► United States Code Annotated, 3-Volumes,

Title 21 Food and Drugs 1 - 356C

Title 21 Food and Drugs 357 - 840

Title 21 Food and Drugs 841 - 847

Chapter 1

9 Volumes Title 21 Food and Drugs C.F.R. 4.1.04 ed.

► Title 21 C.F.R. 1-99 (Food and Drug Admin.)

► Title 21 C.F.R. 100-169 (F.D.A. Food for Human Cons)

► Title 21 C.F.R. 170-199 (FDA Food for Human Cons)

► Title 21 C.F.R. 200-299 (FDA Drugs General)

► Title 21 C.F.R. 300-499 (FDA Drugs for Human use)

► Title 21 C.F.R. 500-599 (FDA Animal Drugs, Foods)

► Title 21 C.F.R. 600-799 (FDA Biologics, Cosmetics)

► Title 21 C.F.R. 800-1299 (FDA Medical Devices)

Title 21 C.F.R. 1300-End (Drug Enforcement Admin.)

Chapter - 2

► Title 21 C.F.R. sec. 201.321 - (Definitions)

Chapter - 3

? Title 21 C.F.R. sec. 301.331 - (Prohibited Acts and Penalties)

Chapter V

► Title 21 C.F.R. sec. 501-351 (Drugs and Devices)